REMARKS

The applicant respectfully requests reconsideration of claims 36-48, 50-56, 58-62, 64 and 65, along with consideration of new claim 77. Matters raised in the present action are now addressed, in the order presented.

A. In view of the earlier election requirement, claims 57 and 66-76 are cancelled. Claims 49 and 63 also are cancelled.

B. The information disclosure statement filed July 26, 2004 is subject to an objection based on alleged failure to include copies of the listed references. The applicant notes the indication that references listed in U.S. Patent No. 6,626,939 (issued on the parent application) have been considered. An effort is underway to locate and provide copies of the remaining references or to identify equivalents (e.g. issued patents based on identified patent applications).

C. All claims have been rejected under the judicially created doctrine of obviousness-type double patenting, based on U.S. Patent No. 6,626,939.

In connection with this rejection, it is asserted in the present action that the conflicting claims are not patentably distinct from each other claiming the identical stent-graft.

This assertion is respectfully traversed. However, the applicant is agreeable to filing a terminal disclaimer.

Accompanying this amendment is a terminal disclaimer, signed on behalf of the assignee of the present application, disclaiming any portion of the term of a patent issuing on this application that otherwise might extend beyond the full statutory term of U.S. Patent No. 6,626,939. This application and the '939 patent are commonly owned. Accordingly, it is submitted that the terminal disclaimer overcomes the obviousness-type double patenting rejection.

D. Claims 36-38, 43-45, 48-49, 52-54, and 63-65 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,527,354 (Fontaine, et al.).

The Fontaine patent discloses a stent formed from a single continuous wire having a hemispherical or "half-round" cross section. The stent is balloon-expandable, not self-expanding. See column 6, beginning at line 39. The stent materials preferably have a "low memory" in that the stent does not try to resume its original shape after it is deformed. This is

said to be important for preventing the stent from recoiling to its compressed condition after implantation (column 7, lines 54-58). Fontaine mentions that the stent can be used "inside a graft" for repairing a pseudo-aneurysm in a common femoral artery (column 7, lines 31-33). The preferred stent material is said to be tantalum wire, although a bioabsorbable material is indicated as an alternative. Fontaine does not teach that its stent is annealed.

Claim 36 defines a stent-graft including a radially compressible and expandable annealed tubular body comprising a bioabsorbable portion. The stent-graft further includes a compliant graft layer that tends to conform to the tubular body as it radially expands and contracts. The tubular body is radially expandable upon deployment at a treatment site to provide radial structural support at an initial level sufficient to fix the stent-graft at the treatment site and maintain body lumen patency. This radial structural support is reduced over time responsive to absorption of the bioabsorbable portion *in-vivo* after deployment. The graft layer *in-vivo* is receptive to growth of body tissue therein and thereabout over time, to form with the body tissue a composite wall adapted to act in lieu of the tubular body to maintain patency of the body lumen.

It is well settled that anticipation requires the disclosure, in the allegedly anticipatory reference, of each and every element of the claim. Under this standard, Fontaine fails to anticipate the stent-graft defined in claim 36.

First, as noted above, Fontaine fails to teach or suggest that its stent is annealed. As noted in the present specification (page 10 at line 20), annealing filaments making up the tubular body relaxes the stresses in the body and sets its shape.

Second, Fontaine lacks any teaching or suggestion of a graft that compliantly tends to conform to the tubular body as the tubular body radially expands and contracts. As noted in U.S. Patent No. 5,957,974 (cited by the examiner in the present action), it is known to couple a compliant but substantially fixed-radius and tightly woven graft to a radially expandable stent. If the graft diameter is not carefully matched with the lumen diameter at the treatment site, either an oversized graft is compressed between the stent and body tissue with undesirable folds of the graft material, or an undersized graft prevents the stent from radially expanding sufficiently to anchor the device (see column 2, lines 9-21).

A compliant graft layer, not fixed as to its radius but instead tending to conform to the tubular body as the body radially expands and contracts, avoids this problem.

Fontaine states that its stent "can be used inside a graft" (column 7, line 33), but teaches absolutely nothing about the graft itself. Nothing in Fontaine motivates the skilled artisan toward any particular type of graft.

Accordingly, the Fontaine patent fails to anticipate the stent-graft of claim 36.

Claims 37-38, 43-45 and 48 depend on claim 36 and are allowable for the reasons given in support of claim 36.

Claim 52 defines a stent-graft with a feature similar to the stent-graft of claim 36 in that the first graft layer is more compliant than the tubular body and tends to conform to the tubular body as the tubular body radially expands and contracts.

Accordingly, Fontaine fails to anticipate the stent-graft of claim 52. Claims 53, 54, 64 and 65 are patentable due to their dependency on claim 52.

E. Claims 36-40, 42, 44-58, 60-63 and 65 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,957,974 (Thompson, et al.).

The Thompson patent discloses a stent-graft including a braided stent and a braided polymeric sleeve. The stent can be a latticework of interbraided metal or polymeric monofilaments. The sleeve can be a braid formed of polymeric multifilament yarns. An adhesive layer between the latticework and sleeve bonds them together.

Claim 36 defines a stent-graft in which a tubular body, which comprises a bioabsorbable portion, is radially expandable at a treatment site to provide radial structural support sufficient for fixing the stent-graft and maintaining the body lumen. As noted in the specification (e.g. page 9, lines 8-14), the radial support function is temporary, because the stent or other tubular body gradually loses its capacity to provide the structural support as the bioabsorbable portion is absorbed *in-vivo*.

There is a need for an alternative structure to eventually assume the radial support function. The graft layer provides such structure, in that it is receptive to growth of body tissue therein and thereabout *in-vivo*. The result, over time, is a composite wall including the graft layer and the body tissue, adapted to act in lieu of the tubular body to provide the radial

structural support. As noted in the specification, vessel compliance and functional stresses are generally transferred from the stent portion (tubular body) to the new tissue. While the stent bioabsorbs over time, the compliant graft and natural tissue remain in the vessel at the treatment site and form a composite vessel wall. Again, see page 9, lines 8-14.

Thus, claim 36 defines a stent-graft with more than an annealed tubular body comprising a bioabsorbable portion. Further, the bioabsorbable portion is sufficient to materially alter the structure of the tubular body *in-vivo*, in terms of substantially (over time) reducing the capacity of the tubular body to provide radial structural support to the tissue surrounding it. Another claimed feature is that the graft layer is receptive to body tissue growth, and accommodates tissue growth therein and thereabout at the treatment site to form a composite wall adapted to provide the radial structural support when the tubular body no longer is able to do so. Indeed, preferred embodiments may include tubular bodies formed entirely of bioabsorbable material, each tubular body eventually being completely absorbed to leave only the composite wall at its treatment site.

None of the latticework embodiments disclosed in Thompson is formed of bioabsorbable filaments. Nonetheless, the examiner relies on Figure 13 of Thompson, which shows a latticework 106 composed of structural strands, a sleeve 108 composed of textile strands, and an auxiliary strand 110. The specification text associated with Figure 13 reads, in part:

> An auxiliary strand 110 is interbraided with the textile strands. Strand 110 can be formed of a radiopaque material, e.g. tantalum, to improve fluoroscopic imaging of the stent-graft. Alternatively, biological or bioabsorbable strands can be interwoven in this fashion. (Column 13, lines 59-63, emphasis added)

The only other reference to bioabsorbable material in Thompson also is focused upon an auxiliary element or enhancement to a latticework or sleeve. As noted in column 5, lines 39-46:

> A variety of enhancements are provided within the scope of the present invention, e.g. incorporating one or more radiopaque strands in the latticework or sleeve, incorporating bioabsorbable materials, providing axial runners to enhance resistance to radial compression, and coating the completed stent-graft or individual strands, to reduce deployment forces and lower the inflammatory response of tissue to the implanted device.

In Figure 13, auxiliary strand 110 is visible along the latticework, which is surrounded by the sleeve. The examiner appears to rely on this figure as a teaching of the claimed

bioabsorbable portion of the tubular body. However, as pointed out above, the features of claim 36 are not met by the mere presence of bioabsorbable material in a tubular body. Rather, such presence must be of sufficient magnitude or degree to effect the aforementioned material structural change in the tubular body as a whole, *in-vivo*.

This is neither taught nor suggested in Thompson. The only use disclosed for bioabsorbable material, is of a single auxiliary strand interbraided with the biocompatible but not bioabsorbable strands of the latticework or sleeve. This type of use does not insure, nor does it suggest, a bioabsorbable portion sufficient to provide a tubular body that is materially altered over time *in vivo*, in terms of a substantially reduced capacity to provide radial structural support. Further, Thompson does not motivate the skilled artisan toward latticework structures completely or even substantially absorbable *in-vivo*, because the reference does not discuss any procedures for which a diminishing capacity to provide radial support would be advantageous.

Accordingly, the Thompson patent does not anticipate the stent-graft of claim 36.

Claims 37-40, 42, 44-48 and 50-51 depend on claim 36 and are patentable for the reasons given in support of claim 36.

Claim 52, like claim 36, provides that the radial structural support of the tubular body is reduced over time responsive to absorption of its bioabsorbable portion *in-vivo* following deployment, and further that the first graft layer is receptive to growth of body tissue therein and thereabout over time, to form with the body tissue a composite wall adapted to provide the radial structural support in lieu of the tubular body.

Accordingly, claim 52 is patentable for the reasons given in support of claim 36. Claims 53-56, 58-62, and 65 are patentable by virtue of their dependency on claim 52.

F. Claims 41, 43, 59 and 64 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Thompson in view of U.S. Patent No. 6,245,103 (Stinson).

The Stinson patent discloses a bioabsorbable self-expanding stent.

In the present action, Stinson is relied upon to show a bioabsorbable adhesive in connection with claims 41 and 59, and various specific bioabsorbable materials in connection with claims 43 and 64.

The Stinson patent is focused on stents, and does not disclose devices that combine bioabsorbable stents with more permanent graft layers. Moreover, if the bioabsorbable materials disclosed in Stinson were substituted "for the bioabsorbable material of Thompson" as suggested in the present action (page 6), the result would be a non-bioabsorbable sleeve or latticework incorporating a single auxiliary strand made of one of the bioabsorbable materials disclosed in Stinson. This does not teach the claimed invention. As before, there is no teaching of a tubular body with a bioabsorbable portion sufficient to materially alter the structure of the tubular body *in vivo*. Accordingly, the invention is patentable over the Thompson/Stinson combination for the reasons given immediately above in support of claims 36 and 52. It follows that claims 41, 43, 59 and 64 are patentable over the Thompson/Stinson combination by virtue of their dependency on claims 36 and 52.

New claim 77 further defines the stent-graft of claim 36 in that the tubular body is adapted to be completely absorbed *in-vivo* following deployment. This claim is allowable for the reasons given in support of claim 36, and further because the prior art fails to teach the combination of a completely absorbable tubular body and a compliant, conforming graft layer.

In summary, claims 36-48, 50-56, 58-62, 64, 65 and 77 incorporate subject matter patentable over the prior art of record. An early and favorable action allowing these claims is requested.

Respectfully submitted,

Boston Scientific Scimed, Inc.

Date: June 14, 2005

By: _____

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CERTIFICATE OF MAILING

Pursuant to 37 CFR 1.8, I hereby certify that this Amendment and accompanying Terminal Disclaimer in Application Serial No. 10/674,726 are being deposited with the U.S. Postal Service by first class mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date of deposit indicated below.

Date of Deposit: June 14, 2005

Frederick W. Niebuhr

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